

REMARKS

This Amendment is respectfully submitted in response to the Office Action rendered in the above-identified patent application on August 12, 2003. It is timely submitted in view of the Petition for Extension of Time submitted concurrently herewith.

Claim 1 has been amended to add the clause "in mammalian hair in need thereof". Basis for this amendment may be found in the Specification at p. 1, l. 21 through p. 5, l. 12. Claim 18 has been amended in order to clarify the embodiments of the methods of applicants' invention which are the focus of this application. Claim 18 has been amended to remove the reference to "preventing" pseudofolliculitis barbae. Applicants respectfully reserve the right to present the deleted subject matter in a future application. The Specification has been amended by adding the subject matter set forth in claims 1, 23 and 35 relating to plant families to the Specification.

The Office Action of August 12, 2003 rejected claims 1 and 18 under 35 U.S.C. 112, first paragraph. The Office Action states that the rejection of claim 1 under 35 U.S.C. 112 is based on the reasoning that the specification, "while being enabling for soymilk, does not reasonably provide enablement for all Leguminosae family." [Office Action, p. 2]. The Office Action also rejects claim 1 under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement because the specification "does not contain description of compounds extracted from the solanaceae, gramineae and cucurbitaceae families." [Office Action, p. 3] The rejection of claim 18 was based on the ground that "the specification does not reasonably provide enablement for preventing pseudofolliculitis barbae." [Office Action, p. 3]. Applicants respectfully request reconsideration of the foregoing rejections in light of the amendments to the application and the ensuing discussion.

Applicants respectfully submit that 35 U.S.C. 112 does not require examples for each and every species set forth in the claims of an application. *In re Strabilevitz*, 668 F. 2d 1229, 1232 (CCPA 1982). The leguminosae, solanaceae, gramineae and cucurbitaceae families are themselves plant families. The specification sets forth that the compositions and methods of the invention should contain serine protease inhibitors and exemplifies the soybean species within the leguminosae family. One of ordinary skill in the art should not have to pursue undue experimentation to obtain compositions in accordance with applicants' invention based upon the current specification. Furthermore, the plant species of the recited families are readily available from botany references.

Applicants therefore request reconsideration of the rejection of claim 1 under 35 U.S.C. 112, first paragraph.

Applicants have amended the Specification to recite the solanaceae, gramineae and cucurbitacea families. The basis for this amendment can be found in the Specification as filed in original claims 1, 23 and 35. Applicants therefore request reconsideration of the rejection of claim 1 under 35 U.S.C. 112, first paragraph with respect to the written description requirement.

Applicants have removed reference to prevention of pseudofolliculitis barbae in claim 18 as set forth above. Applicants respectfully submit that this renders the rejection of claim 18 under 35 U.S.C. 112, first paragraph moot and request reconsideration of this rejection in light thereof.

The Office Action of August 12, 2003 also rejected claims 1-3, 6, 7, 9, 15 and 19 under 35 U.S.C. 102(e) as being anticipated by Costanzo (US Patent No. 6,323,219). The basis for this rejection is as follows:

Costanzo discloses topically applying pharmaceutical or cosmetic composition in an amount effective to mammalian skin to effect changes in pigmentation...and soybean milk or other formulations derived directly from legumes is applied to the mammalian skin...Costanzo discloses that extracts from the plant families of Leguminosae, solanaceae, gramineae and cucurbitacea contain serine protease inhibitors...[Office Action, p. 6]

Applicants respectfully request reconsideration of this rejection in view of the foregoing amendments to the claims and the ensuing discussion.

Applicants respectfully submit that nowhere does Costanzo suggest or describe methods to use the compositions of applicants' invention to affect hair. Although Costanzo does mention change in skin pigmentation due to application of certain compositions, Costanzo does not allude in any way to an effect of such compositions upon hair or hair growth. Thus, Costanzo does not teach or suggest applying such compositions to the hair of a mammal in need of a change in appearance and, therefore, does not disclose the methods of applicants' invention. Applicants respectfully submit that they have amended claim 1 to clarify that, according to applicants' methods, the composition is to be applied to mammalian hair in need of a change in appearance. Applicants respectfully suggest that the claimed methods are not anticipated by Costanzo and respectfully request reconsideration of the rejection under 35 U.S.C. 102(e).

The Office Action of August 12, 2003 further rejected claims 4, 5, 8, 10-14, 16-18 and 20-22 under 35 U.S.C. 103(a) as being unpatentable over Costanzo in view of JP 9059166A. The basis for this rejection is as follows:

...Regarding claims 4 and 5, there is no showing demonstrating that the amount of the inhibitor provides unusual results. Regarding claims 11-14, 16-18 and 20-22, since the composition of the prior art is applied to the skin, the composition would exhibit the properties of the composition on the skin.

Costanzo does not teach that the composition comprising the plant extracts contains isoflavones. However, JP 9059166 discloses that soybean extract contains isoflavones...Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the extract of soy bean to apply to the skin in order to effect changes in mammalian hair appearance. One having ordinary skill in the art would have been motivated to include isoflavone in the composition of Costanzo with the expectation that the composition produce changes in the mammalian hair appearance. [Office Action, p. 7]

Applicants respectfully request reconsideration of this rejection in view of the ensuing discussion.

As set forth above, there is no suggestion or teaching in Costanzo to apply the compositions therein to effect changes in the hair's appearance. Furthermore, there is no teaching in Costanzo that would motivate one to combine the teachings therein with JP 9059166. Although Costanzo mentions applying soy-derived compositions to the skin, Costanzo states that the active ingredient therein are "compounds that inhibit trypsin, such as serine protease inhibitors, and in particular, soybean trypsin inhibitor..." [Costanzo, col. 8, l. 44-46]. Costanzo does not cite isoflavones as participating in the methods described therein. The mere presence of isoflavones in soy would not necessarily guide one of ordinary skill in the art toward combining the teachings of Costanzo with the teachings of JP 9059166A.

Furthermore, applicants respectfully submit that JP 9059166A teaches away from the methods and compositions of applicants' invention. As set forth in JP 9059166A, the benefits of a specific type of isoflavone, "malonyl isoflavone glycoside" are quite different from those of the methods of applicants' invention. Specifically, JP 9059166A suggests that this type of isoflavone **stimulates hair growth**:

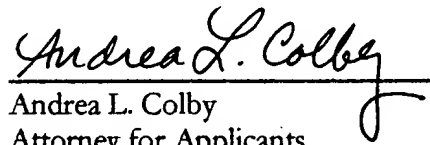
Epithelial cell growth promoter useful as dermal agent comprises malonyl isoflavone glycoside prep'd. from soybean or aq. extract of soybean as the active ingredient...The growth promoter is useful as a skin cosmetic, **stimulator of hair growth**, anti-inflammatory

agent, for preventing skin ageing, skin smoothing and for wound healing. [JP 9059166A, abstract] (emphasis added)

In contrast, the methods of applicants' invention relating to "effecting changes in mammalian hair appearance and hair pigmentation, and **reducing hair growth**, and hair follicle and hair shaft size" are quite unexpected in light of JP 9059166A. Furthermore, nowhere does JP 9059166A mention changes in mammalian hair appearance, hair pigmentation, or hair follicle and hair shaft size. Thus, applicants respectfully submit that one of ordinary skill in the art would not be motivated to combine the teachings of Costanzo, which does not mention hair treatment at all, with JP 9059166A, which merely discusses utilizing a specific type of isoflavone for stimulating hair growth. Applicants respectfully contend that one of ordinary skill in the art would not have been led to the methods and compositions of their invention by the teachings of Costanzo and JP 9059166A, taken separately or together.

Based upon the foregoing discussion and amendments to the application, applicants respectfully request reconsideration of the foregoing rejections. An early allowance is earnestly solicited.

Respectfully submitted,


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February 12, 2004